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| 10/594,215 | 01/03/2007 | Kazuo Suzuki | 2006_1634A | 7223 |

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| EXAMINER | |
|---|---|
| DICKINSON, PAUL W | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/594,215 | SUZUKI ET AL. | |
| | Examiner | Art Unit | |
| | PAUL DICKINSON | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/26/2006 and 4/28/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112, Scope of Enablement for Oral Administration*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving insulin resistance by oral administration of the insulin resistance-improving agent, it does not reasonably provide enablement for improving insulin resistance by any route of administration of the insulin resistance-improving agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to improve insulin resistance by any route of administration of the insulin resistance-improving agent commensurate in scope with the claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to a method for the prophylaxis of a disease or symptom resulting from insulin resistance. The relative skill of those in the art is high, that of an MD or PhD. That factor is outweighed, however, by the unpredictable nature of the art.

2. The breadth of the claims

The claims encompass a method for improving insulin resistance, which comprises administering to a patient in need thereof an insulin resistance-improving agent comprising a pharmaceutically acceptable anion exchange resin as an active ingredient. This encompasses any route of administration, such as oral, intravenous, topical, etc.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for a method of improving insulin resistance comprising administering the disclosed agents to a patient by any route of administration. No reasonably specific guidance is provided concerning useful therapeutic protocols for improving insulin resistance in a patient, other than by oral administration of the disclosed agents. The latter is corroborated by the working examples.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be administered by any route of administration to improve insulin resistance in a patient, commensurate in scope with the claims. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art

would have to engage in undue experimentation, with no assurance of success.

***Claim Rejections - 35 USC § 112, Scope of Enablement for Prophylaxis***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving and treating a disease or symptom resulting from insulin resistance, does not reasonably provide enablement for prophylaxis of a disease or symptom resulting from insulin resistance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to carry out a method for prophylaxis of a disease or symptom resulting from insulin resistance, commensurate in scope with the claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[2]

[2] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to a method for the prophylaxis of a disease or symptom resulting from insulin resistance. The relative skill of those in the art is high, that of an MD or PhD. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites

http://www.diabetes.org/diabetes-basics/genetics-of-diabetes.html (accessed 9/3/2010), which teaches that all type 2 diabetes patients have a genetic predisposition to the disease. The disease is ultimately triggered by something in the patient's environment.

2. The breadth of the claims

Since the instant specification provides no limiting definition of the term prophylaxis (i.e. prevention), the Examiner will adopt the broadest reasonable interpretation for same. Webster's Ninth New Collegiate Dictionary defines "prevention" as "to keep from happening or existing", i.e., to completely eradicate.

The claims are thus very broad insofar as they claim the prophylaxis of a disease or symptom resulting from insulin resistance, i.e., the complete eradication of same. While such prophylaxis might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the "real world" in which patients live.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for prophylaxis of a disease or symptom resulting from insulin resistance. No reasonably specific guidance is provided concerning useful therapeutic protocols for such prophylaxis, other than improving or treating the disease or symptom. The latter is corroborated by the working examples.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used for prophylaxis of a disease or symptom resulting from insulin resistance as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

5. Suggested alternative language

Since the term "treating" is inclusive of various administrative timing schemes and thus provides adequate coverage for all reasonably successful therapies (prophylactic or active), the examiner recommends deleting the term "prophylaxis" and simply recite "improvement" or "treatment" instead.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6-7, 11, 13-14, 23, and 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 4, 7, 11, 14, 23, and 26, the term "derivative" is indefinite because it is unclear how far one can deviate from the parent compound without the "derivative" being so far removed therefrom as to be a completely different compound.

Regarding claims 4, 11, and 23, the phrase "...of which typical example includes..." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 6, 13, and 25, the phrase "is used simultaneously, separately, or successively" does not make sense. it is unclear in what way the hypoglycemic agent is used. Is the agent administered to the patient? Further, the hypoglycemic agent is used simultaneously, separately, or successively in relation to what? Is this in relation to the administration of the insulin resistance-improving agent of claim 1? If so, it should read "simultaneously, separately, or successively to the administration of the insulin resistance-improving agent of claim 1".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 2003011308 (WO '308; document already in record; US 20040191209 is an English equivalent). WO '308 discloses that administration of colestimide (a pharmaceutically acceptable anion exchange resin that has a bile acid-absorbing ability; a pharmaceutically acceptable anion exchange resin that is synthesized by a polymerization reaction of an epichlorohydrin derivative and an amine) inhibited blood sugar elevation after eating in patients with hypercholersterolemia complicated by type 2 diabetes (examples). WO '308 also describes that similar effects were achieved when a sulfonylurea drug was used in combination (examples 1 and 4). Type 2 diabetes is a disease caused by insulin resistance as described in paragraph 36 of the instant specification. The above method described by WO 308 is a method for improving insulin resistance (instant claim 1), a method for suppressing the onset of or treating insulin resistance syndrome (instant claim 8), and a method for the treatment of a disease or symptom resulting from insulin resistance (instant claim 16) and meets every limitation of instant claims 1-26.

Claims 1-3, 6-10, 13-22, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Garg (Cholestyramine Therapy for Dyslipidemia in Non-Insulin-dependent Diabetes Mellitus, Ann. Inter. Med., 1994, 121, 416-422; document already in record). Garg discloses that it is possible to lower cholesterol and control diabetes by administration of cholestyramine (a pharmaceutically acceptable anion exchange resin

that has a bile acid-absorbing ability) (see Results and Discussion). Diabetes is a disease caused by insulin resistance as described in paragraph 36 of the instant specification. The above method described by Garg is a method for improving insulin resistance (instant claim 1), a method for suppressing the onset of or treating insulin resistance syndrome (instant claim 8), and a method for the treatment of a disease or symptom resulting from insulin resistance (instant claim 16) and meets every limitation of instant claims 1-26.

Claims 1-26 are rejected under 35 U.S.C. 102(b) as being unpatentable over JP 2002-537390 (JP '390; a machine translation is provided). JP '390 discloses that the compound of Formula (I) (an oral hypoglycemic agent) can be used to treat insulin resistance either by itself or in combination with the hypolipemia/hypolipoproteinemia drugs cholestyramine and cholestipol (a pharmaceutically acceptable anion exchange resin that has a bile acid-absorbing ability; a pharmaceutically acceptable anion exchange resin that is synthesized by a polymerization reaction of an epichlorohydrin derivative and an amine) (claims, paragraphs 5 and 94-95). The above method described by JP '390 is a method for improving insulin resistance (instant claim 1), a method for suppressing the onset of or treating insulin resistance syndrome (instant claim 8), and a method for the treatment of a disease or symptom resulting from insulin resistance (instant claim 16) and meets every limitation of instant claims 1-26.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 217-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul W. Dickinson
Examiner
Art Unit 1618

September 3, 2010